

FINAL STATEMENT OF REASONS
TITLE 27 CALIFORNIA CODE OF REGULATIONS

**SECTION 25805(b). SPECIFIC REGULATORY LEVELS: CHEMICALS
CAUSING REPRODUCTIVE TOXICITY**

This is the Final Statement of Reasons for a specific regulatory level for one chemical, di-*n*-hexyl phthalate (DnHP), listed as known to the State to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986 (hereinafter “the Act” or Proposition 65; Health and Safety Code, section 25249.5 *et seq.*). On May 16, 2008, the Office of Environmental Health Hazard Assessment (OEHHA) issued a Notice of Proposed Rulemaking for a proposed regulatory level for di-*n*-hexyl phthalate, a chemical listed as known to cause reproductive toxicity, to be added to Title 27, California Code of Regulations, section 25805(b)¹. The Initial Statement of Reasons set forth the grounds for the proposed regulation. A public comment period was provided from May 16, 2008 through June 30, 2008. No request for a public hearing was received and no written comments were received by OEHHA.

ALTERNATIVES DETERMINATION

In accordance with Government Code, section 11346.5(a)(7), OEHHA has, throughout the adoption process of this regulation, considered available alternatives to determine whether any alternative would be more effective in carrying out the purpose for which the regulations were proposed, or would be as effective and less burdensome to affected private persons than the proposed action. OEHHA has determined that no alternative considered would be more effective, or as effective and less burdensome to affected persons, than the proposed regulation.

For chemicals listed under the Act as known to cause reproductive toxicity, the Act exempts discharges to sources of drinking water and exposures of people without provision of a warning if the exposure (or discharged amount) will produce no observable effect on reproduction assuming exposure at 1,000 times the level in question.(Health and Safety Code, section 25249.10(c)).

The purpose of this regulation is to provide a “safe harbor” level for a particular chemical exposure. This regulation establishes the numerical Maximum Allowable Dose Level for one reproductive toxicant, di-*n*-hexyl phthalate. At or below this level, the Act does not require a warning regarding reproductive toxicity or prohibit discharges to sources of drinking water based on reproductive toxicity concerns associated with di-*n*-hexyl phthalate. Thus, this level will allow persons subject to the Act to determine whether a given discharge to sources of drinking water or exposure to people involving these chemicals is subject to the warning requirement and discharge prohibition provisions of

¹ All further references are to sections of Title 27 (formerly Title 22) of the California Code of Regulations, unless otherwise noted.

the Act related to the risk of reproductive toxicity (Health and Safety Code sections 25249.6).

Although Section 25803 describes principles and assumptions for conducting risk assessments to derive safe harbor levels for reproductive toxicity, many businesses subject to the Act do not have the resources to perform these assessments. Yet each business with ten or more employees must determine whether its activities or products are subject to the discharge prohibition or warning requirements of the Act. Given the wide use of the chemical covered by this regulation, the absence of this regulation would leave numerous businesses without an efficient way of determining if they are in compliance with the Act without the expenditure of significant resources on their part.

LOCAL MANDATE DETERMINATION

OEHHA has determined this regulatory action will not pose a mandate on local agencies or school districts nor does it require reimbursement by the State pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code. OEHHA has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from this regulatory action. It should be noted that Proposition 65 provides an express exemption from the warning requirement and discharge prohibition for all state and local agencies. Thus, these regulations do not impose any mandate on local agencies or school districts.

Note: The footnotes a and b, proposed in the original text, were withdrawn from the final text.